

H.R.1362

National MS and Parkinson's Disease Registries Act (Introduced in House)
HR 1362 IH

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H. R. 1362

To amend the Public Health Service Act to provide for the establishment of permanent national surveillance systems for multiple sclerosis, Parkinson's disease, and other neurological diseases and disorders.

IN THE HOUSE OF REPRESENTATIVES

March 5, 2009

Mr. VAN HOLLEN (for himself, Mr. BURGESS, Mrs. MALONEY, Mr. UPTON, Mr. CARNAHAN, and Mr. KING of New York) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to provide for the establishment of permanent national surveillance systems for multiple sclerosis, Parkinson's disease, and other neurological diseases and disorders.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,
SECTION 1. SHORT TITLE.

This Act may be cited as the `National MS and Parkinson's Disease Registries Act'.
SEC. 2. FINDINGS.

Congress makes the following findings:

- (1) Multiple sclerosis (referred to in this section as `MS') is a progressive, disabling disease that affects the brain and the spinal cord causing loss of myelin, damage to axons, and cerebral atrophy.
- (2) MS is a prime-of-life disease with an average age of onset at 30 to 35 years of age.
- (3) More than 10,000 individuals in the United States are diagnosed with MS annually, and it is thought that more than 400,000 individuals in the United States have MS.
- (4) Parkinson's disease is a chronic, progressive neurological disease. The primary pathologic feature of Parkinson's disease is degeneration and premature death of dopamine-producing brain cells.

(5) Parkinson's is the second-most common neurodegenerative disease in the United States.

(6) It is estimated that more than 1,000,000 Americans are currently fighting Parkinson's disease, and 60,000 Americans are newly diagnosed every year.

(7) Although estimates exist, there is no confirmed data regarding prevalence or diagnosed cases of Parkinson's disease or MS.

(8) The causes of Parkinson's disease and MS are not well understood.

(9) There is no known cure for Parkinson's disease or MS.

(10) Studies have found relationships between both MS and Parkinson's disease and environmental and genetic factors, but those relationships are not well understood.

(11) Better data are needed to understand the economic impact of Parkinson's disease, MS, and other neurological diseases.

(12) There are several drugs currently approved by the Food and Drug Administration for the treatment of MS, which have shown modest success in reducing relapses, slowing progression of disability, and limiting the accumulation of brain lesions.

(13) Currently, state-of-the-art treatment for Parkinson's disease is based on a 40-year-old pharmaceutical therapy, which only treats some of the motor symptoms of Parkinson's disease. Deep brain stimulation surgery is available for certain patients and treats some symptoms of Parkinson's disease.

(14) No therapies exist that will slow or stop progression of Parkinson's disease. There is no effective, lasting therapy for all features of Parkinson's disease.

(15) Central nervous system drugs, including therapies for MS, Parkinson's disease, and other neurological diseases, are the slowest in the drug development pipeline, taking an average of 15 years post discovery for new therapies to reach the market.

(16) Several small and uncoordinated MS and Parkinson's disease registries, surveillance systems, and databases exist in the United States and throughout the world.

(17) A single national system to collect and store information on the incidence and prevalence of MS, Parkinson's disease, or other neurological diseases in the United States does not exist.

(18) The Agency for Toxic Substances and Disease Registry (ATSDR) has established a series of small pilot studies, beginning in fiscal year 2006, to evaluate the feasibility of various methodologies to create an MS surveillance system at the national level.

(19) The national surveillance system methodology resulting from the MS pilot studies should be expanded upon and developed into a national surveillance system for Parkinson's disease.

(20) The establishment of separate, coordinated national surveillance systems for Parkinson's disease and MS will help--

(A) to identify the incidence and prevalence of these diseases in the United States;

(B) to collect demographic and other data important to the study of MS and Parkinson's disease;

(C) to produce epidemiologically sound data that can be used to compare with cluster information, data sets of the Department of Veterans Affairs, environmental exposure data, and other information;

(D) to promote a better understanding of causes, prevention, and treatment of disease;

(E) to better understand public and private resource impact;

(F) to collect information that is important for research into genetic and environmental risk factors;

(G) to enhance biomedical and clinical research by providing a basis for population comparisons;

(H) to enhance efforts to develop better diagnosis and progression biomarkers for MS and Parkinson's disease; and

(I) to enhance efforts to find treatments and a cure for MS and Parkinson's disease.

SEC. 3. SURVEILLANCE SYSTEMS.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended--

(1) by redesignating the second and third sections 399R (added by section 2 of Public Law 110-373 and section 3 of Public Law 110-374) as sections 399S and 399T, respectively; and

(2) by adding at the end the following:

`SEC. 399U. SURVEILLANCE OF NEUROLOGICAL DISEASES.

`(a) Multiple Sclerosis National Surveillance System-

`(1) IN GENERAL- Not later than 1 year after receipt of the report described in subsection (c)(3), the Secretary, acting through the Director of the Agency for Toxic Substances and Disease Registry and in consultation with a national voluntary health organization with experience serving the population of individuals with multiple sclerosis (referred to in this section as `MS'), shall--

`(A) develop a system to collect data on MS including information with respect to the incidence and prevalence of the disease in the United States;

`(B) establish a national surveillance system for the collection and storage of such data to include a population-based registry of cases of MS in the United States;

`(C) assist in application of MS national surveillance system methodologies for the development, piloting, and implementation of a national Parkinson's disease national surveillance system under subsection (b); and

`(D) provide analysis regarding expansion of national disease surveillance systems for other neurological diseases and disorders utilizing the MS and Parkinson's disease national surveillance systems' process and structure.

`(2) PURPOSE- It is the purpose of the registry established under paragraph (1)(B) to gather available data concerning--

`(A) MS, including the incidence and prevalence of MS in the United States;

`(B) the age, race or ethnicity, gender, military service if applicable, and family history of individuals who are diagnosed with the disease; and

`(C) other matters as recommended by the Advisory Committee established pursuant to subsection (c).

`(b) Parkinson's Disease National Surveillance System-

`(1) IN GENERAL- Not later than 1 year after the receipt of the report described in subsection (c)(3), the Secretary, acting through the Director of the Agency for Toxic Substances and Disease Registry and in consultation with a national voluntary health organization with experience serving the population of individuals with Parkinson's disease, shall--

`(A) develop a system to collect data on Parkinson's disease including information with respect to the incidence and prevalence of the disease in the United States;

`(B) establish a national surveillance system for the collection and storage of such data to include a population-based registry of cases of Parkinson's disease in the United States; and

`(C) provide analysis regarding expansion of national disease surveillance systems for other neurological diseases utilizing the MS and Parkinson's disease national surveillance systems' process and structure.

`(2) PURPOSE- It is the purpose of the registry established under paragraph (1)(B) to gather available data concerning--

`(A) Parkinson's disease, including the incidence and prevalence of Parkinson's disease in the United States;

`(B) the age, race or ethnicity, gender, military service if applicable, and family history of individuals who are diagnosed with the disease; and

`(C) other matters as recommended by the Advisory Committee established pursuant to subsection (c).

`(c) Advisory Committee-

`(1) ESTABLISHMENT- Not later than 180 days after the date of the enactment of this section, the Secretary, acting through the Director of the Agency for Toxic Substances and Disease Registry, shall establish a committee to be known as the Advisory Committee on Neurological Disease Registries (referred to in this section as the `Advisory Committee'). The Advisory Committee shall be composed of at least one member, to be appointed by the Secretary, acting through the Director of the Agency for Toxic Substances and Disease Registry, representing each of the following:

`(A) National voluntary health associations that focus solely on MS and have demonstrated experience in MS research, care, or patient services.

`(B) National voluntary health associations that focus solely on Parkinson's disease and have demonstrated experience in Parkinson's disease public policy, research, care, or patient services.

`(C) The National Institutes of Health, to include, upon the recommendation of the Director of the National Institutes of Health, representatives from the Office of Portfolio Analysis and Strategic Initiatives, the National Institute of Neurological Disorders and Stroke, the National Institute of Environmental Health Sciences, the National Institute on Aging, and the National Institute of Allergy and Infectious Diseases.

`(D) The Department of Veterans Affairs, to include representatives from the Parkinson's Disease Research Education and Clinical Centers and the MS Centers of Excellence.

`(E) The Department of Defense, to include representatives from the Parkinson's disease and MS research programs.

`(F) The Food and Drug Administration.

`(G) The Centers for Disease Control and Prevention, to include representatives from the Agency for Toxic Substances and Disease Registry.

`(H) Patients with MS and Parkinson's disease or their family members.

`(I) Clinicians with expertise on MS and Parkinson's disease.

`(J) Research scientists with experience conducting translational research or creating systems that support translating basic discoveries into treatments.

`(K) Epidemiologists with experience in data registries.

`(L) Geneticists or experts in genetics who have experience with the genetics of MS and Parkinson's disease.

`(M) Statisticians.

`(N) Bioethicists.

`(O) Attorneys.

`(P) Other individuals, organizations, or agencies with an interest in developing and maintaining the MS and Parkinson's disease national surveillance systems.

`(Q) Experts in additional neurological diseases, as appropriate, based on development and

implementation of national surveillance systems for other neurological diseases and disorders.

`(2) DUTIES- The Advisory Committee shall review information and make recommendations to the Secretary concerning--

`(A) the development and maintenance of the MS and Parkinson's disease national surveillance systems;

`(B) the use and coordination of existing databases that collect or maintain information on neurological diseases and disorders;

`(C) the type of information to be collected and stored in the systems;

`(D) the manner in which such data is to be collected;

`(E) the use and availability of such data including guidelines for such use; and

`(F) the application of MS and Parkinson's disease registry methodologies to benefit other neurological diseases and disorders, including analysis of how other neurological disease surveillance systems or registries can be developed, piloted, and implemented nationally utilizing the MS and Parkinson's disease national surveillance systems' process and structure.

`(3) REPORT- Not later than 1 year after the date on which the Advisory Committee is established, the Advisory Committee shall submit a report to Congress concerning the review conducted under paragraph (2) that contains the recommendations of the Advisory Committee with respect to the results of such review.

`(d) Grants- Notwithstanding the recommendations of the Advisory Committee under subsection (c), the Secretary, acting through the Director of the Agency for Toxic Substances and Disease Registry, may award grants to, and enter into contracts and cooperative agreements with, public or private nonprofit entities for the collection, analysis, and reporting of data on MS and Parkinson's disease.

`(e) Coordination With State, Local, and Federal Registries-

`(1) IN GENERAL- In establishing the MS and Parkinson's disease national surveillance systems under subsections (a) and (b), the Secretary, acting through the Director of the Agency for Toxic Substances and Disease Registry, shall--

`(A) identify, build upon, expand, and coordinate existing data and surveillance systems, surveys, registries, and other Federal public health and environmental infrastructure wherever possible, including--

`(i) the 2 MS surveillance pilot studies initiated in fiscal year 2006 by the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry;

`(ii) the Parkinson's disease and MS databases of the Department of Veterans Affairs;

`(iii) current Parkinson's disease registries and surveillance systems, including the Nebraska and California State registries;

`(iv) current MS registries, including the New York State MS Registry and the North American Research Committee on MS (NARCOMS) Registry; and

`(v) any other existing or relevant databases that collect or maintain information on neurological diseases and disorders identified by researchers or recommended by the Advisory Committee pursuant to subsection (c); and

`(B) provide for and conduct outreach in support of research access to Parkinson's disease and MS data as recommended by the Advisory Committee established pursuant to subsection (c) to the extent permitted by applicable statutes and regulations and in a manner that protects personal privacy consistent with applicable privacy statutes and regulations.

`(2) COORDINATION WITH OTHER FEDERAL AGENCIES- Notwithstanding the recommendations of the Advisory Committee established pursuant to subsection (c), and

consistent with applicable privacy statutes and regulations, the Secretary shall ensure that epidemiological and other types of information obtained under subsections (a) and (b) are made available to agencies such as the National Institutes of Health, the Food and Drug Administration, the Department of Veterans Affairs, and the Department of Defense.

`(f) Definition- For the purposes of this section, the term `national voluntary health association' means a national nonprofit organization with chapters, other affiliated organizations, or networks in States throughout the United States.

`(g) Authorization of Appropriations- There is authorized to be appropriated to carry out this section \$5,000,000 for each of fiscal years 2010 through 2014.'

